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SECTION 6

510(k) Summary

Proprietary Name	PEEK CAGE FOR THE VERTEBRAL SPINE NEOSPACE
Date Prepared	May 28, 2014
510(K) Number	K132852
Submitter	NEOORTHO Produtos Ortopedicos S/A Rua Angelo Domingos Durigan, 607 Cascatinha Curitiba-PR, Brazil 82020-340 Telephone: +55 41 3535-1033 Fax: +55 41 3535-1018
Official Contact	Tara Conrad TechLink International Consulting 18851 NE 29th Avenue Suite 720 Aventura, FL 33180 TEL– (305) 377-0077
Common Name	Intervertebral body fusion device
Regulation Number & Product Codes	MAX -21 CFR §888.3060 ODP- 21 CFR §888.3080
Classification Panel	Orthopedic
Predicate Device Identification	K071983 Aesculap PEEK Spinal Implant System; K082848 Nubic by Signus

Device Description

The PEEK CAGE FOR THE VERTEBRAL SPINE NEOSPACE is an intervertebral body fusion device that is implanted into the vertebral body space to improve stability of the spine while supporting fusion. Components are offered in a variety of shapes and sizes to meet the requirements of the individual patient anatomy. Components are manufactured from PEEK - Optima (per ASTM F2026).

Indications for Use Statement

The PEEK Cage for the Vertebral Spine NeoSpace PLIF, TLIF, and ALIF devices are indicated for spinal fusion procedures at one or two contiguous levels from L2-S1, in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have Grade 1 Spondylolisthesis or retrolisthesis at involved levels. Patients must have undergone a regimen of six months of non-operative treatment prior to treatment in the lumbar spine. The PLIF devices may be used singularly or in pairs. All lumbar devices are to be used with supplemental fixation cleared for use in the lumbar spine.

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The Cervical devices are indicated for spinal fusion procedures at one level in the cervical spine from C3 to T1 for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Patients must have undergone a regimen of six weeks of non-operative treatment prior to treatment in the cervical spine. One cervical device is used per intervertebral space. All cervical devices are to be used with supplemental fixation cleared for use in the cervical spine.

All lumbar and cervical devices are intended for use with autogenous bone graft.

Substantial Equivalence

The fundamental scientific technology, design, and materials of the subject device are substantially equivalent to the legally marketed predicates.

Performance Testing

The following tests were performed on the worst case subject devices: static compression, static compression-sheer, static torsion, dynamic compression, dynamic compression-sheer and dynamic torsion testing per ASTM F2077 and subsidence testing per ASTM F2267. The testing demonstrated substantially equivalent performance of the subject device as compared the legally marketed predicate devices.

Conclusion

The subject device and predicate devices share the same indications for use, primary implant design and equivalent material of manufacture.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 29, 2014

NEOORTHO Produtos Ortopedicos S/A
% Ms. Tara Conrad
TechLink International Consulting
18851 Northeast 29th Avenue, Suite 720
Aventura, Florida 33180

Re: K132852
Trade/Device Name: PEEK Cage for the Vertebral Spine NeoSpace
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX, ODP
Dated: April 25, 2014
Received: April 29, 2014

Dear Ms. Conrad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132852

Device Name
PEEK Cage for the Vertebral Spine NeoSpace

Indications for Use *(Describe)*
The PEEK Cage for the Vertebral Spine NeoSpace PLIF, TLIF, and ALIF devices are indicated for spinal fusion procedures at one or two contiguous levels from L2-S1, in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have Grade 1 Spondylolisthesis or retrolisthesis at involved levels. Patients must have undergone a regimen of six months of non-operative treatment prior to treatment in the lumbar spine. The PLIF devices may be used singularly or in pairs. All lumbar devices are to be used with supplemental fixation cleared for use in the lumbar spine.

The Cervical devices are indicated for spinal fusion procedures at one level in the cervical spine from C3 to T1 for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Patients must have undergone a regimen of six weeks of non-operative treatment prior to treatment in the cervical spine. One cervical device is used per intervertebral space. All cervical devices are to be used with supplemental fixation cleared for use in the cervical spine.

All lumbar and cervical devices are intended for use with autogenous bone graft.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

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